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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,698	01/23/2002	Tatsuki Shiota	Q68142	8252

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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,698

Applicant(s)

SHIOTA ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 4-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, Claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

2. Applicant's election with traverse of Group II, claims 1-3 and 7-11, and compound 2269 as the species in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the compounds are represented by a single formula and have a same biological activity. This is not found persuasive because a single formula can encompass structurally distinct compounds when variables are employed in the formula.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on elected species.

Claim Objection

1. Claim 1 is objected to because of the following informalities: the employment of bracket “[]” in claim 1 is informal. Also employment of parenthetical expression in claims is considered informal.

Double Patenting Rejections

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-2, 7-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 27-37 of U.S. Patent No. 6,451,842.

Although the conflicting claims are not identical, they are not patentably distinct from each other because '182 claims compounds and their pharmaceutical salts that are substantially overlap with the compounds herein employed, and encompasses the elected species. See the claims. Note, the particular function, or intended use of a compound or composition do not further limit subject matter drawn to the compound or composition.

Claim Rejections 35 U.S.C. 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling the composition herein for treating the diseases listed in claim 8-11, does not reasonably provide enablement for preventing such diseases, or for treating or preventing other diseases which concerned with CCR3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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1. Claims 6, 8-10 and 27-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating multiple sclerosis, does not reasonably provide enablement for preventing multiple sclerosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims are directed to a method of preventing various diseases, including allergic diseases, inflammatory diseases, and AIDS. The specification discloses the compositions herein are CCR# antagonistic and may be useful in alleviating or suppressing the symptoms of the diseases. However, the specification fails to adequately teach how to use the method to prevent such diseases. Each of the listed diseases may have different etiologies, the specification or the claims does not provide sufficient evidences, or working examples showing the CCR3 antagonist herein would be useful for preventing such diseases. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

2. Claim 7 defines diseases treatable by the composition herein as “disease concerned with CCR3.” The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Particularly, the specification fails to identify what other diseases beside those listed in claims 8-11 are CCR3 concerned diseases. Attention is directed to *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

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- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The claim recites for treating CCR3 concerned diseases. Applicants fail to provide information allowing skilled artisan to ascertain such disease without undue experimentation. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. Particularly, one of ordinary skill in the art would have to identify those diseases that may be concerned with CCR3. The instant claims read on all CCR3 concerned diseases, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-2 and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The phrase “arbitrary number of halogen atoms,” in claim 1 has not been clearly defined in the specification, or in the claim. Particularly, it is not clear what is the “arbitrary number.” The claims are indefinite as to the number of halogen therein. Note the claimed composition

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herein recite “ a composition contains” without any further limitation, and would read on compounds. Note, the particular function of the compounds or composition (CCR3 antagonist herein) does not further limit subject matters drawn to the compounds or composition.

Claim Rejections 35 U.S.C. 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 2, 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiota et al. (US 6,451,842, or WO 99/25686, IDS).

13. Shiota teaches therapeutical compounds with a general formula essentially identical to the formula (I) herein employed (see, pages 7-20 in WO 99/25686). The general formula encompasses the particular species herein elected.

14. Shiota does not teach expressly the particular species herein elected.

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15. However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the compound since the compound are within the general formula and Shiota teaches examples that structurally close to the elected species. See, compounds 243-247. Note, the particular function, or intended use of a compound or composition do not further limit subject matter drawn to the compound or composition.

16. Claims 1, 2 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al (US 6,166,015).

17. Rogers teaches pyrrolidine derivative CCR3 antagonist useful for treating asthma. The general formula (I) in Rogers substantially overlap in scope with the general formula herein, particularly, A is 9I) $-N(R^2)C(O)-$ and B is $-C(O)-$ or $-S(O)_n-$. See, particularly, the abstract, column 2, lines 18 to 55, and the claims.

18. Rogers does not teach expressly to make a pharmaceutical composition comprising the compounds herein disclosed.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the compounds disclosed by Rogers, which are also encompassed by the general formula herein because such compounds are known to be useful as CCR3 antagonist and are useful for treating CCR3 associated diseases, such as asthma.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

A handwritten signature in black ink, appearing to read 'Shengjun Wang', is written over a rectangular stamp area.

Shengjun Wang

October 11, 2003